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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,199	07/30/2003	Juergen Wulf	GK-OEH-163 / 500814.20065	2020
7590 Gerald H. Kiel, Esq. REED SMITH LLP 599 Lexington Avenue New York, NY 10022-7650			EXAMINER LEVKOVICH, NATALIA A	
			ART UNIT 1743	PAPER NUMBER
			MAIL DATE 05/03/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/630,199

Applicant(s)

WULF ET AL.

Examiner

Natalia Levkovich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks filed on 02/20/2007 have been acknowledged by the Examiner.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

3. The drawings remain objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the light sources arranged at a distance of the 'nozzle pitch', as recited in the amended claim 22, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

4. Claim 22 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

As amended, claim 22 recites the 'alignment unit' having two light sources 'arranged with a distance alike the nozzle pitch '. No support was found for the above

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limitation. The specification discloses an 'adjustment comb' with two light sources aligned with two non-adjacent wells, and does not specify any correlation between the alignment of light sources and the 'nozzle pitch.' The limitation is considered to be new matter and must be cancelled from the claim.

5. Claims 1-26 remain rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended claim 1 now recites 'an optical system by which the luminescent light that is excited in the wells of the microplate due to the dispensing is imaged for observation of a large-area rectangular field of the microplate, wherein said large-area rectangular field includes a plurality of columns being progressively dispensed'. The underlined limitation is unclear because 'large' is a relative term. How would an artisan of the ordinary skill construe as to what number of columns should be considered sufficient to form the 'large area'?

The claim further recites an 'imaging camera provided in a camera block, the camera block comprising the imaging camera and the optical system, the imaging camera being directed to the underside of the microplate across from the dispensing unit for repeatedly receiving an image of all wells of the large-area rectangular field of the microplate imaged by the optical system, so that a course of luminescence over time for each individual specimen in all wells of the large-area rectangular field is measurable while simultaneously ongoing dispensing occurs successively column by column'.

The underlined limitation replete with functional language directed to the manner in which the device operates. Apparatus claims are defined by their structure and not their function. Additionally, the structural elements and their inter-relationships which would provide for the functionality remain unclear. For example, it is not clear whether or not it is the Applicant's intention to claim the imaging camera configured specifically for storing the images and the optical system configured for creating the images. It is also unclear how the process of 'repeatedly receiving an image' can be coordinated with the process of measuring the 'course of luminescence over time' ('while simultaneously ongoing dispensing occurs successively column by column'), without a controller.

In claim 22, line 4, the 'nozzle pitch' lacks antecedent basis. It is also unclear as to what dimension associated with the nozzle is meant. Does Applicant intend to claim the degree of inclination, or the greatest height of the nozzles?

Claim Rejections - 35 USC § 103

6. Claims 1-5, 8-9, 11-20 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giebeler et al. (US 20020176801).

Giebeler discloses (as was previously discussed) an integrated fluid delivery and analysis system comprising a light tight housing with a door, a dispense assembly, a light source, a detector, and an optical system "adapted to direct light from the light source to a sample holder such as a microplate positioned in an examination site, and from the sample holder to the detector..." (See [0030], [0033]). "FIG. 5 shows a perspective view of an exemplary material exchange system ['table system' – Ex.]

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552... for supporting one or more material holders 556 ..."- [0069]. The dispense assembly comprises "a compact modular folded pipettor head ['dispensing comb' having a symmetric structure – Ex.]- (See [0046]; Figures 6-7).

"The pipettor ['dispensing comb' – Ex.] may include a linear array of 8, 16, or any other number of appropriately spaced pipettor elements to correspond to a single row of a 96-well, 384-well, or any other number of well microplate, respectively. The pipettor also may include a linear array of 12 or 24 appropriately spaced pipettor elements to correspond to a single column of a 96-well or 384-well microplate, respectively. The pipettor also may include a number and arrangement of pipettor elements to correspond to a portion of a row or column, or two or more rows or columns, or another type of sample holder. The dispense assemblies may be easily interchangeable on the dispense assembly driver to accommodate microplates and other sample holders with different numbers and/or densities of wells"-[0060].

"The analyzer module preferably includes top and bottom optics ['optical system' – Ex.], enabling a variety measurement modes, including... bottom illumination and bottom detection...". The "sample holders" [wells – Ex.] may have "optically transparent bottoms, such as glass or thin plastic bottoms..."-{0087].

The system also includes an imaging detector, such as a photodiode array, or a "suitable CCD ['imaging camera' – Ex.], rectangular or square", the detector being "located directly under the well " ['underside of the microplate across from the dispensing unit' – Ex.] - (see [0092], [0246] - [0247]).

Although ,Giebeler does teach a two dimensional imager (such as CCD, photodiode array, or avalanche diode array, as discussed above) capable of imaging an area which would include a plurality of wells , the relative size of the 'area' is not specifically disclosed. However, it would have been within the ordinary skill of an artisan at the time the invention was made to have configured the imager /detector of Giebeler such that the size of its active / working surface area would be commensurate with the size of the object to be imaged (that is, a certain area of the micro-plate), in order to optimize the system, in terms of, on the one hand, increasing the spatial resolution and, on the other hand, reducing the cost and size of the detector.

With respect to claim 3, Giebeler teaches that an "eight-channel dispense assembly for a 96-well microplate may be used to dispense into a 384-well microplate by combining a first dispense into a first set of eight wells, an offset, and a second dispense into the second set of eight wells"-(See [0065]).

As to claim 4, Giebeler teaches that "the pipettor also may include a number and arrangement of pipettor elements to correspond to ... two or more rows or columns, or another type of sample holder" which reads on 'dispensing combs which are arranged parallel to one another, rigidly coupled with one another".

Referring to claims 5 and 8, Giebeler teaches "a variety of dispense and/or analysis strategies, independently or in conjunction with one another', for example, the dispense may be "of the same reagent from a reservoir with the same format as a microplate, to all wells in the sample holder, or even multiple reagents at different times" -[0127].

In regards to claim 19, Figure 11 shows a sample-plate holding fixture (or carriage) 1101 designed to accommodate multiwell plates of standard dimensions (e.g., 86 by 129 millimeters). To accommodate other sized plates, an adaptor plate (not shown) is mounted within fixture 1101, the non-standard plate fitting within the adaptor plate"- [0098].

7. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giebeler in view of Wohlstadter et al (20040022677).

Giebeler does not teach means of autofocusing and alignment. Wohlstadter discloses optics that "collects an image and focuses that image' automatically (See [0520]) and "mechanisms to align and orient the assay plates with the photodetector(s) " (See [0016]). As to light emitting diodes, focusing lenses, batteries and power switches, these elements are routinely used in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed means of alignment and auto-focusing , in the modified apparatus of Giebeler, in order to provide automatic control of high quality imaging system.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giebeler in view of Marouiss et al. (US 20010048899).

Giebeler does not teach controllable valves for dispensing units, however such valves are routinely used in the art (see, for example, [0163], [0171], [0176] of Marouiss). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed controllable valves with the dispensing units in the modified

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apparatus of Giebeler, in order to gain more flexibility in monitoring the dispensing process.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giebeler in view of Marouiss, and further view of Schick (US 20030230521).

Giebeler does not teach a waste trough, however, waste containers are commonly used in the liquid handling systems (see, for example, [0044]-[0045] of Schick). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed waste containers arranged in a suitable manner, in the modified apparatus of Giebeler, in order to provide a proper waste removal.

Allowable Subject Matter

10. Claim 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Although the closest prior art, Marouiss et al., disclose a linear dispensing unit adapted to microplates with different distances between the wells through offsetting the entire unit relative to a microplate, Marouiss et al do not teach, or fairly suggest a linear dispensing unit which includes two parallel units arranged offset to one another by half of the distance between the dispensing nozzles, as recited in claim 10.

Response to Arguments

11. Applicant's arguments filed on 02/20/2007 have been fully considered but they are not persuasive, or moot in view of new grounds of rejection.

Applicant argues that 'Giebeler ... does not teach or suggest combining simultaneous dispensing with simultaneous detection of multiple wells' and that 'specifically, Giebeler does not teach or suggest that a course of luminescence over time for each individual specimen is all wells of the large-area rectangular field is measurable while simultaneously ongoing dispensing occurs successively column by column'. Examiner notes that this functional limitation does not further limit the structure and, therefore, does not impart patentable moments to the apparatus claims.

Applicant argues that 'Giebeler do not provide a method for observing fast light emitting reactions of a reactant added to the samples in the wells or light emitting reactions of samples to which different fluids are successively applied for measuring the reaction intensity profile', and that, 'furthermore, all the embodiments of Giebeler do not provide a method for observing fast light emitting reactions of a reactant added to the samples in the wells or light emitting reactions of samples to which different fluids are successively applied for measuring the reaction intensity profile'. Examiner notes that the above mentioned functional limitations are not recited in the instant claims.

Applicant argues that the 'system of 'Giebeler does not provide a free underside of the microplate for an optical imaging'. Examiner notes that the 'free underside' is not

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claimed. Additionally, Giebeler teaches "bottom detection" / imaging, for example, in [0087], or [0092] (see the above discussion).

Applicant argues that 'Giebeler fails to teach or suggest using such sample holders [that is, with clear bottoms – Ex.] to combine top dispensing with bottom measurement simultaneously with imaging of a large-area rectangular field by a camera', as well as the reference allegedly does not teach 'top and bottom optics'. With respect to the optics, transparent bottoms and 'large area field, Examiner directs Applicant's attention to the art rejection discussed above. .

Applicant argues that 'Giebeler fails to teach or suggest a table system for moving the microplate and dispensing unit relative to one another'. Examiner notes that Figure 5 shows microplate 556 supported by carriages / 'table system' 554 and, thus, movable relative to the dispensing head / 'comb' 504.

Applicant argues that 'Giebeler does not teach a controllable pump. Examiner notes that the 'controllable pump' is not recited in the latest version of the Applicant's claims. Additionally, any pump is subject to some control. For example, it can be stopped, or started.

Applicant argues that 'Wohlstadter is not prior art since it was published on February 5, 2004 which is after the filing date of the present invention July 20, 2003'. Examiner note that Wohlstadter et al. enjoy the filing date of June 28, 2002, and can be used as a prior art under 35 U.S.C. 103(a).

Applicant argues that 'does not cure the deficiencies of Giebeler. Specifically, the cited references fail to teach or suggest that a course of luminescence over time for

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each individual specimen in all wells of the large-area rectangular field is measurable while simultaneously ongoing dispensing occurs ... column by column'. Examiner notes that this reference was cited to address autofocusing, and not the underlined limitation.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

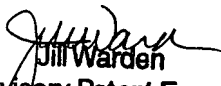
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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